UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

VALERIE PALMIERI, individually and on behalf of all others similarly situated,

COMPLAINT AND JURY DEMAND

Plaintiff.

CLASS ACTION

v.

INTERVET INC. d/b/a MERCK ANIMAL HEALTH, a subsidiary of MERCK & CO., INC.,

CIVIL ACTION NO.

Defendant.

Plaintiff Valerie Palmieri ("Plaintiff"), individually and on behalf of all others similarly situated (collectively, the "Class," as more fully defined below), brings this class action complaint against Defendant Intervet Inc., d/b/a Merck Animal Health, a subsidiary of Merck & Co., Inc. ("Intervet" or "Defendant"). Plaintiff makes the following allegations upon personal knowledge as to her own acts, upon information and belief, and her attorneys' investigation as to all other matters, alleging as follows:

I. NATURE OF THE ACTION

1. Bravecto is the trade name for the drug fluralaner, which includes a pesticide called isoxazoline. In May 2014, the U.S. Food and Drug Administration ("FDA") approved the marketing and sale of Bravecto tablets for dogs, and Bravecto topical solutions for cats and dogs (collectively "Bravecto"), for the treatment and prevention of flea and tick infestations. Bravecto is produced and marketed by Defendant Intervet Inc. d/b/a Merck Animal Health, which is a subsidiary of Merck & Co., Inc.

1

- 2. Defendant advertises and markets Bravecto nationally as a safe chewable tablet for dogs, or a topical application that prevents and kills ticks and fleas for up to three months, while competing products provide only one month of protection.
- 3. Bravecto is a pesticide that is absorbed into the blood stream of animals that are treated with it and causes toxicity in insects that bite those animals, including uncontrolled neural activity and, eventually, death. Because of the method by which it kills insects, Bravecto also presents a risk of neurological toxicity in the animals that are treated with it that Defendants failed to disclose to consumers, including Plaintiff and the other class members.
- 4. Because Defendant failed to disclose the risks of Bravecto to consumers and misrepresented the safety of Bravecto, consumers would be reasonable in purchasing Bravecto to treat their pets in a safe manner.
- 5. On September 20, 2018—more than four years after Defendant began marketing and selling Bravecto—the FDA issued an alert (the "FDA Press Release") on the potential neurological adverse events associated with isoxazoline medications to treat flea and ticks, including Bravecto.¹ In that press release, the FDA stated that it was requesting that manufacturers change their labels to "highlight neurological events because these events were seen consistently across the isoxazoline class of products" and "to provide veterinarians and pet owners with the information they need to make treatment decisions for each pet on an individual basis." The FDA

¹ FDA, Animal Drug Safety Communication: FDA Alerts Pet Owners and Veterinarians About Potential for Neurologic Adverse Events Associated with Certain Flea and Tick Products (Sept. 20, 2018), https://www.fda.gov/animal-veterinary/cvm-updates/animal-drug-safety-communication-fda-alerts-pet-owners-and-veterinarians-about-potential-neurologic.

Press Release also indicated that certain manufacturers—but not Defendant—had made the requested label change.

- 6. Defendant now discloses a risk of some neurologic adverse reactions including tremors, ataxia, and seizures from Bravecto Products.²
- 7. The FDA, European government agencies, and, likely, Defendant, have received thousands of reports relating to adverse events from isoxazoline products, including Defendant's Bravecto product. A significant number of these adverse events relate to neurological symptoms.
- 8. Consumers of Bravecto—including Plaintiff and the other class members—paid a premium for Bravecto, based on its purported safe extended prevention and control of flea and tick infestations compared to other products. Defendant, however, misrepresented or omitted the risk of neurological adverse reactions that Bravecto causes.
- 9. Every consumer who purchased Bravecto without being informed of the true facts about its health and safety risks prior to purchase was injured at the point of sale when, instead of obtaining a safe flea and tick medication, they obtained Defendant's unreasonably dangerous and defective product.
- 10. Further, consumers who purchased Bravecto experienced consequential damages caused by Bravecto's undisclosed safety issues.
- 11. By misrepresenting the safety of its products, and omitting or failing to disclose the dangers that Bravecto posed to pets, Defendant defrauded Plaintiff and the other class members, deprived them of the benefit of their bargain, and/or unjustly enriched themselves at Plaintiffs' and

3

² Bravecto, FAQ, https://us.bravecto.com/faq (last visited Dec. 6, 2019); https://www.merck-animal-health-usa.com/pdfs/canine/BravectoDogPI_152451%20R11_8.5x11.pdf (last visited Dec. 6, 2019).

the other class members' expense. Plaintiff, individually and on behalf of the other class members she seeks to represent, seeks monetary damages, statutory penalties, and injunctive relief as set forth herein.

II. <u>JURISDICTION AND VENUE</u>

- 12. Jurisdiction is proper in this Court pursuant to the Class Action Fairness Act, 28 U.S.C. § 1332(d), because at least one Class member is of diverse citizenship from one Defendant, there are more than 100 class members, and the aggregate amount in controversy exceeds \$5,000,000, exclusive of interest and costs. Also, jurisdiction is proper in this Court pursuant to 28 U.S.C. § 1331, because Plaintiff's Magnuson-Moss Act claim arises under federal law. This Court has supplemental jurisdiction over Plaintiff's state law claims under 28 U.S.C. § 1367.
- 13. This Court has personal jurisdiction over Defendant because Defendant is headquartered in the State of New Jersey and has purposefully availed itself of the privilege of conducting business in the State of New Jersey. Some, if not most, of the actions giving rise to the Complaint took place in this District, including but not limited to Defendant's manufacturing, distribution, advertising and representations regarding Bravecto, and Defendant's use of a call center to receive complaints from customers regarding adverse reactions. Most, if not all, of Plaintiff's claims arise out of Defendant operating, conducting, engaging in, or carrying on a business or business venture in this State, or having an office or agency in this State, committing a tortious act in this State, and causing injury to property in this State arising out of Defendant's own acts and omissions outside this State. At or about the time of such injuries, Defendant was engaged in solicitation or service activities within this State, or else products, materials, or things processed, serviced, or manufactured by Defendant anywhere were used or consumed within this State in the ordinary course of commerce, trade, or use.

14. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(a), because a substantial part of the events or omissions giving rise to these claims occurred in this District, Defendant has caused harm to class members residing in this District, and Defendant is a resident of this District under 28 U.S.C. § 1391(c)(2), because it is subject to personal jurisdiction in this District.

III. PARTIES

Plaintiff

15. Valerie Palmieri is a resident and citizen of the State of Connecticut, residing in Monroe, Connecticut. Plaintiff, reasonably relying upon Defendant's uniform misrepresentations of the Bravecto product, and without knowledge of the safety issues Defendant's Bravecto product has, treated her pet dog Jake with one Bravecto tablet on or around November 13, 2016.

Defendant

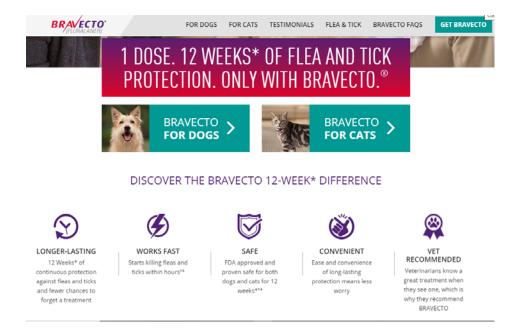
16. Intervet Inc. identifies its address in Madison, New Jersey, including on its Bravecto packaging. Intervet's registered business address with the State of New Jersey is Kenilworth, New Jersey. Intervet does business under the name Merck Animal Health and is a subsidiary of Merck & Co., Inc. Intervet manufactures, distributes, markets, and sells Bravecto to consumers and veterinarians across the United States from its New Jersey headquarters.

IV. <u>COMMON FACTUAL ALLEGATIONS</u>

A. Defendant Misleadingly Markets Bravecto as a Safe Treatment for Fleas and Ticks on Dogs and Cats.

17. Defendant's central marketing theme for Bravecto is the purported safety of its quick-acting, effective, and long-lasting benefits in preventing and controlling flea and tick infestations in dogs and cats, as compared to other products that require more frequent application.

18. In fact, Defendant touts Bravecto's "safety" front and center on its marketing, claiming that it "FDA approved and proven safe for both dogs and cats for 12 weeks."



- 19. Under the "FAQ" page of its website, Defendant states in response to the question "HOW SAFE IS BRAVECTO?" that "BRAVECTO has a wide margin of safety in dogs who weigh at least 4.4 lb. and cats who weigh at least 2.6 lb. It is also approved for puppies and kittens aged 6 months or older. BRAVECTO Chew is approved for use in breeding, pregnant, and lactating dogs."⁴
- 20. In May 2014, the FDA approved Defendant's sale of Bravecto chewable tablets for dogs and topical solution for cats and dogs for the treatment and prevention of flea and tick infestations.
- 21. Bravecto chewable tablets are flavored for easier digestion by dogs. Consumers are instructed to give one tablet or apply the topical solution every twelve weeks—unlike the

³ Bravecto, https://us.bravecto.com (last visited Dec. 27, 2019).

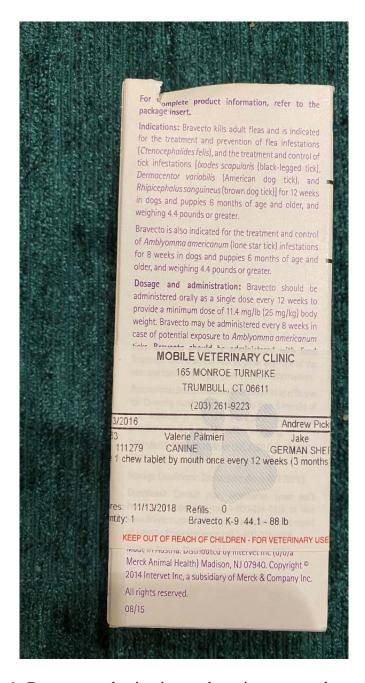
⁴ Bravecto FAQs, https://us.bravecto.com/faq (last visited Dec. 27, 2019).

common monthly application of other products. In addition to its potency to last three months,

Defendant also touts Bravecto's immediate effectiveness in killing fleas and ticks.

- 22. Defendant formulated Bravecto—a pesticide—in both an ingestible, chewable tablet form for dogs, and a topical solution for dogs and cats. Bravecto poisons insects through their nervous systems causing uncontrolled neural activity and death. Because of Bravecto's formulation as a toxic pesticide that it is ingested or applied to the skin of animals to prevent and kill fleas and ticks, it presents a risk of neurological toxicity in the animals that are treated with it, which is not known to consumers.
- 23. At no time during the time period relevant to this action did Defendant's Bravecto packaging provide any warning of adverse reactions. To wit, and by way of example:





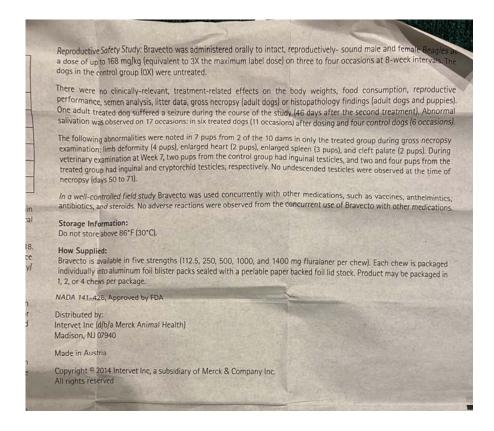
24. Defendant's Bravecto packaging insert also misrepresented or omitted these risks by asserting that in a "well-controlled U.S. field study," "there were no serious adverse reactions":

Cauton: Tederal (USA) law restricts this drug to use by or on the order of a licensed veterinarian. Tederal (USA) law restricts this drug to use by or on the order of a licensed veterinarian. Description: Each chew is formulated to provide a minimum dose of 114 mg/lb (25 mg/hg) body weight: Each chew is formulated to provide a minimum dose of 114 mg/lb (25 mg/hg) body weight: methyl-M-[2-oxo-2-(2-22-cifluocethylamino) ethylbercamide. Indications: Brayecto kills adult flees and is reseated for the treatment and prevention of nea infestations (Ctenocephalities/fels) and the treatment and control of the infestations [block-legged tick), Dermocetion variobilis [Anterican dog tick); and Rhipicephalus songuines (brown dog tick)] for 12 weeks in dogs and pupples 6 months of age and older, and weighing 4.4 pounds or greater. Bravects in also indicated for the treatment and control of Amblyomma americanum (lone star tick) infestations for Amblyomma and Administration. Bravects in a minimum and Administration. Bravects of a manimum and a single diose every 12 weeks according to the Dosage Schedule below to provide a minimum alone of 114 mg/fb (25 mg/hg) body veright. Bravecto should be administered every 8 weeks in case of potential exposure to Amblyomma americanum; ticks [see effectiveness]. Bravecto should be administered with food. Dosage Schedule Body Weight Ranges (lib) Fluralaner Content (mg) Chews Administered Bravetto should be administered with food. Dosage Schedule Body Weight Ranges (lib) Fluralaner Content (mg) Chews Administered changes and the special product of the product in the original pactaging until use, in order to prevent children from getting direct access to the product. Polatobic voluntarian content of the product of the product of the product. Warnings: Not for human use. Keep this and all drugs out of the reach of children. Keep the product in the original pactaging until use, in order to prevent children from getting direct access to the product. Polatobic voluntarian contents of	BRAVECTO° (FLURALANER) Chews		17	1
Description: Each chew is formulated to provide a minimum dose of 11.4 mg/lb [25 mg/lg] body weight. Each chew is formulated to provide a minimum dose of 11.4 mg/lb [25 mg/lg] body weight. Each chew is formulated to provide a minimum dose of 11.4 mg/lb [25 mg/lg] body weight. The chemical name of fluralener is (a)-4.15-(3.6-36chlorophenyl)-5-(trifluoromethyl)-4.5-dihydroisoxazol-3-y/l-2. methyl-4-(2-ono-2-4/2,2-trifluorochydramino) ethylibenzamide. Indications: Bravecto kils adult feas and is repeated for the treatment and prevention of rice intestations (Chemoepholides felia), and highicepholides anguines (brown dog tick). Jorna and pupples 6 months of age and older, and itsk), and highicepholides felia, and itsk), and highicepholides felia, and itsk, and highicepholides felia, a				-
Descriptions Each chew is formulated to provide a minimum dose of 11.4 mg/lb (25 mg/kg) body weight. Each chew is formulated to provide a minimum dose of 11.4 mg/lb (25 mg/kg) body weight. The chemical name of fluralparer is (a)-4-(5-(3,5-dichloropheryl)-5-(trifluoromethyl)-4.5-dihydroisoxazol-3-yl]-2. The chemical name of fluralparer is (a)-4-(5-(3,5-dichloropheryl)-5-(trifluoromethyl)-4.5-dihydroisoxazol-3-yl]-2. Indications: Bravetto shill adult fleas and is flucated for the treatment and prevention of nea infestations (10 percentage) (10 percent	Caution: Endered (USA) law rectricite this down to use by or on the order of a licensed veterinarian.			
The chemical name of fluralance is (a)-4.6-5.3,-dichloropheniv)-5-(trifluorometriv)-6-000-2(2.2-trifluoroethylamino) ethylbenzamide. Indications: Bravecto kills adult fleas and is insucated for the treatment and prevention of free infestations (Cotenoepholities felis), and the treatment and control of tick infestations (Nodes exapularis (black-legged tick), Dermocritor veriobilis (American dog tick), and Rhipicepholus sanguineus (prown dog tick)] for 12 weeks in dogs and puppies 6 months of age and older, and weighing 4.4 pounds or greater. Bravecto is also indicated for the treatment and control of Amblyomma americanum (lone star tick) infestations for 8 weeks in dogs and puppies 6 months of age and older, and weighing 4.4 pounds or greater. Dosage and Administration: Dosage and Administration: Bravecto have be administered sirpliyas a single dose every 12 weeks according to the Dosage Schedule below to provide a minimum dose of 11.4 mg/lb (25 mg/hg) body weight. Bravecto should be administered every 8 weeks in case of potential exposure to Amblyomma americanum ticks (see Effectiveness). Bravecto should be administered with food. Dosage Schedule Body Weight Ranges (lb) Fluralaner Content (mg) Chews Administered 4.4-9.9 11.2-5 One Fluralaner Content (mg) Chews Administered Channels Cha				
Indications: Indications: Bravecto kills adult fleas and is macased for the treatment and prevention of flea infestations (Crenocepholides fells), and the treatment and control of tick infestations (knodes scopularis (black-legged tick), Dermace/tior variabilis (American dog the treatment and control of Amblyomma americanum (lone star tick) infestations for 8 weeks in dogs and puppies 6 months of age and older, and weighing 4.4 pounds or greater. Bravecto is also indicated for the treatment and control of Amblyomma americanum (lone star tick) infestations for 8 weeks in dogs and puppies 6 months of age and older, and weighing 4.4 pounds or greater. Bravecto is also indicated for the treatment and control of Amblyomma americanum (lone star tick) infestations for Additions. Bravecto should be administration: Bravecto should be administered avery 8 weeks in case of potential exposure to Amblyomma americanum ticks (see Effectiveness). Bravecto should be administered with food. Dosage Schedule Body Weight Ranges (lb) Fluralaner Content (mg) Chews Administered habitation with too one between the season of the product. Varnings: Treatment with Bravecto may begin at any time of the year and can continue year round without interruption. Contraindications: There are no known contraindications for the use of the product. Varnings: Not for human use. Keep this and all drugs out of the reach of children. Keep the product in the original packaging until use, in order to prevent children from getting direct access to the product. Do not eat, drink or smoke while handling the product. Wash hands thoroughly with soap and water immediately after use of the product. Precautions: Brav	Each chew is formulated to provide a m	(1)_4-[5-(3.5-dichlorophenyl)-5-(trifluo	romethyl)-4,5-dihydroisoxazol-3-yl]-2-	
tick), and knipicepholus asyguineus (brown dog tick)] for 12 weeks in dogs and pupples 6 months of age and older, and weighing 4.4 pounds or greater. Bravecto is also indicated for the treatment and control of Amblyomma americanum (lone star tick) infestations for 8 weeks in dogs and pupples 6 months of age and older, and weighing 4.4 pounds or greater. Bravecto should be administered orally as a single dose every 12 weeks according to the Dosage Schedule below to provide a minimum dose of 11.4 mighlo [25 mg/lag) body weight. Bravecto may be administered every 8 weeks in case of potential exposure to Amblyomma americanum ticks (see Effectiveness). Bravecto should be administered with food. Dosage Schedule Body Weight Ranges (lib) Fluralaner Content (mg) Chews Administered with food. Dosage Schedule Body Weight Ranges (lib) Fluralaner Content (mg) Chews Administered channels and the season of	metnyi-N-[2-0x0-2-[2,2,2-trifluoroethy	lamino) ettyjoenzam		
B weeks in dogs and puppies 6 months of age and older, and weighing 4.9 points of 9.0 posage and Administration: Bravecto should be administered vally as a single dose every 12 weeks according to the Dosage Schedule below to provide a minimum dose of 11.4 mg/lb (25 mg/kg) body weight. Bravecto may be administered every 8 weeks in case of potential exposure to Amblyomma americanum ticks (see Effectiveness). Bravecto should be administered with food. Dosage Schedule Body Weight Ranges (lb) Fluralaner Content (mg) Chews Administered channels 4.49.9 112.5 One 4.49.9 12.5 One 5.22.0 - 44.0 500 One 5.22.0 - 44.0 500 One 5.28.0 - 123.0 Dose 123.	the treatment and control of tick infesta tick), and <i>Rhipicephalus sanguine</i> us (bro weighing 4.4 pounds or greater.	own dog tick)] for 12 weeks in dogs and pr	uppies 6 months of age and older, and	In a well-cone hour intervention
Dosage and Administration: Bravecto should be administered arallyas a single dose every 12 weeks according to the Dosage Schedule below to provide a minimum dose of 11.4 mg/lb (25 mg/kg) body weight. Bravecto may be administered every 8 weeks in case of potential exposure to Amblyomma americanum ticks (see Effectiveness). Bravecto should be administered with food. Dosage Schedule Body Weight Ranges (lb) Fluralaner Content (mg) Chews Administered 4.4 - 9.9 112.5 One 4.4 - 9.9 12.5 One 5.22.0 - 44.0 5.00 One 5.22.0 - 44.0 5.00 One 5.24.0 - 88.0 1.000 One 5.28.0 1.23.0 One Treatment with Bravecto may begin at any time of the year and can continue year round without interruption. Contraindications: There are no known contraindications for the use of the product. Warnings: Not for human use. Keep this and all drugs out of the reach of children. Keep the product in the original packaging until use, in order to prevent children from getting direct access to the product. Do not eat, drink or smoke while handling the product. Wash hands thoroughly with soap and water immediately after use of the product. Precautions: Bravecto has not been shown to be effective for 12-weeks duration in pupples less than 6 months of age. Bravecto is not effective against Amblyomma americanum ticks beyond 8 weeks after dosing (see Effectiveness). Adverse Reactions: In a well-controlled U.S. field study, which included 294 dogs (224 dogs were administered Bravecto every 12 weeks and 70 dogs were administered an oral active control every 4 weeks and were provided with a bits a with the product overy 12 weeks and 200 dogs were administered an oral active control every 4 weeks and were provided with a bits a without over 12 weeks and 200 dogs were administered an oral active control every 4 weeks and were provided with a bits a without and a providence of the providence weight and the providence of the providence which a bits a without weeks and 200 dogs were administered an oral active control every 4 weeks and 200 dogs wer	Bravecto is also indicated for the trea 8 weeks in dogs and puppies 6 months of	tment and control of Amblyomma americ of age and older, and weighing 4.4 pounds	or greater.	Additiona
Bravecto may be administered every 8 weeks in case of potential exposure to Amblyonima americanum ticks (see Effectiveness). Bravecto should be administered with food. Dosage Schedule Body Weight Ranges (Ib) Fluralaner Content (mg) Chews Administered 4.4 – 9.9 112.5 One 22.0 – 44.0 500 One 3-22.0 – 44.0 500 One 48 hour 72 hours *Dogs over 123.0 lb should be administered the appropriate combination of chews Treatment with Bravecto may begin at any time of the year and can continue year round without interruption. Contraindications: There are no known contraindications for the use of the product. Warnings: Not for human use. Keep this and all drugs out of the reach of children. Keep the product in the original packaging until use, in order to prevent children from getting direct access to the product. Do not eat, drink or smoke while handling the product. Wash hands thoroughly with soap and water immediately after use of the product. Precautions: Bravecto has not been shown to be effective for 12-weeks duration in puppies less than 6 months of age. Bravecto is not effective against Amblyonima americanum ticks beyond 8 weeks after dosing (see Effectiveness). Adverse Reactions: In a well-controlled U.S. field study, which included 294 dogs (224 dogs were administered Bravecto every 12 weeks and 70 dogs were administered an oral active control every 4 weeks and were provided with a tell water and a circum and active control every 4 weeks and were provided with a tell water and a circum and active control every 4 weeks and were provided with a tell water and a circum and active control every 4 weeks and were provided with a tell water and a circum and active control every 4 weeks and every provided with a tell water and a circum and active control every 4 weeks and every provided with a tell water and a circum and active control every 4 weeks and every provided with a tell water and a circum and active control every 4 weeks and every provided with a tell water and a circum and active control eve	Dosage and Administration: Bravecto should be administered orally a	as a single dose every 12 weeks according to	2000年 100万年 100万年 100万万万万万万万万万万万万万万万万万万万万万万万万	SafetyHea Clinical P
Bravecto should be administered with food. Dosage Schedule Body Weight Ranges (Ib) Fluralaner Content (mg) Chews Administered inhibitor channels 4.4 – 9.9 112.5 One \$9.9 - 22.0 250 One \$22.0 - 44.0 500 One \$24.0 - 88.0 1000 One \$88.0 - 123.0 1400 One *Dogs over 123.0 Ib should be administered the appropriate combination of chews Treatment with Bravecto may begin at any time of the year and can continue year round without interruption. Contraindications: There are no known contraindications for the use of the product. Warnings: Not for human use. Keep this and all drugs out of the reach of children. Keep the product in the original packaging until use, in order to prevent children from getting direct access to the product. Do not eat, drink or smoke while handling the product. Wash hands thoroughly with soap and water immediately after use of the product. Precautions: Bravecto has not been shown to be effective for 12-weeks duration in puppies less than 6 months of age. Bravecto is not effective against Amblyomma americanum ticks beyond 8 weeks after dosing (see Effectiveness). Adverse Reactions: In a well-controlled U.S. field study, which included 294 dogs (224 dogs were administered Bravecto every 12 weeks and evider expressions).	Bravecto may be administered every 8		Amblyomma americanum ticks (see	half-life effective
Body Weight Ranges (lb) Fluralaner Content (mg) Chews Administered 4.4 – 9.9 112.5 One 5.9.9 – 22.0 250 One 5.22.0 – 44.0 500 One 5.88.0 – 123.0° 1400 One *Dogs over 123.0 lb should be administered the appropriate combination of chews Treatment with Bravecto may begin at any time of the year and can continue year round without interruption. Contraindications: There are no known contraindications for the use of the product. Warnings: Not for human use. Keep this and all drugs out of the reach of children. Keep the product in the original packaging until use, in order to prevent children from getting direct access to the product. Do not eat, drink or smoke while handling the product. Wash hands thoroughly with soap and water immediately after use of the product. Precautions: Bravecto has not been shown to be effective for 12-weeks duration in pupples less than 6 months of age. Bravecto is not effective against Amblyomma americanum ticks beyond 8 weeks after dosing (see Effectiveness). Adverse Reactions: In a well-controlled U.S. field study, which included 294 dogs (224 dogs were administered Bravecto every 12 weeks and 70 dogs were administered an oral active control every 4 weeks and were provided with a sist walkala than the product or channels inhibitor channing inhibitor channels. Fluralane inhibitor channels inhibitor channels. Further well-controlled U.S. field study, which included 294 dogs (224 dogs were administered Bravecto every 12 weeks and evider.	Bravecto should be administered with fo	ood.		
### Channels A.4 - 9.9	Dosage Schedule			Fluralane
>9.9 - 22.0 250 One >22.0 - 44.0 500 One >44.0 - 88.0 1000 One >88.0 - 123.0* 1400 One *Dogs over 123.0 lb should be administered the appropriate combination of chews Treatment with Bravecto may begin at any time of the year and can continue year round without interruption. Contraindications: There are no known contraindications for the use of the product. Warnings: Not for human use. Keep this and all drugs out of the reach of children. Keep the product in the original packaging until use, in order to prevent children from getting direct access to the product. Do not eat, drink or smoke while handling the product. Wash hands thoroughly with soap and water immediately after use of the product. Precautions: Bravecto has not been shown to be effective for 12-weeks duration in puppies less than 6 months of age. Bravecto is not effective against Amblyomma americanum ticks beyond 8 weeks after dosing (see Effectiveness). Adverse Reactions: In a well-controlled U.S. field study, which included 294 dogs (224 dogs were administered Bravecto every 12 weeks and 70 dogs were administered an oral active control every 4 weeks and were provided with a tick earlier between the reliable to the reliable	Body Weight Ranges (lb)	Fluralaner Content (mg)	Chews Administered	channels
Section 200 Section 3 Se	4.4 - 9.9	112.5	One	Effective
>22.0 - 44.0 500 One on dogs effective demonstance Selective product Selecti	>9.9 - 22.0	250	One	Bravecto
*Dogs over 123.0 lb should be administered the appropriate combination of chews Treatment with Bravecto may begin at any time of the year and can continue year round without interruption. Contraindications: There are no known contraindications for the use of the product. Warnings: Not for human use. Keep this and all drugs out of the reach of children. Keep the product in the original packaging until use, in order to prevent children from getting direct access to the product. Do not eat, drink or smoke while handling the product. Wash hands thoroughly with soap and water immediately after use of the product. Precautions: Bravecto has not been shown to be effective for 12-weeks duration in puppies less than 6 months of age. Bravecto is not effective against Amblyomma americanum ticks beyond 8 weeks after dosing (see Effectiveness). Adverse Reactions: In a well-controlled U.S. field study, which included 294 dogs (224 dogs were administered Bravecto every 12 weeks and evidence and organ active control every 4 weeks and were provided with a tiple pulse) the product of	000 440		One	laudiatu
*Dogs over 123.0 lb should be administered the appropriate combination of chews Treatment with Bravecto may begin at any time of the year and can continue year round without interruption. Contraindications: There are no known contraindications for the use of the product. Warnings: Not for human use. Keep this and all drugs out of the reach of children. Keep the product in the original packaging until use, in order to prevent children from getting direct access to the product. Do not eat, drink or smoke while handling the product. Wash hands thoroughly with soap and water immediately after use of the product. Precautions: Bravecto has not been shown to be effective for 12-weeks duration in puppies less than 6 months of age. Bravecto is not effective against Amblyomma americanum ticks beyond 8 weeks after dosing (see Effectiveness). Adverse Reactions: In a well-controlled U.S. field study, which included 294 dogs (224 dogs were administered Bravecto every 12 weeks and overland the study of the stilk cell public and so evider.	>22.0 - 44.0	500	Offic	on dogs
*Dogs over 123.0 lb should be administered the appropriate combination of chews Treatment with Bravecto may begin at any time of the year and can continue year round without interruption. Contraindications: There are no known contraindications for the use of the product. Warnings: Not for human use. Keep this and all drugs out of the reach of children. Keep the product in the original packaging until use, in order to prevent children from getting direct access to the product. Do not eat, drink or smoke while handling the product. Wash hands thoroughly with soap and water immediately after use of the product. Precautions: Bravecto has not been shown to be effective for 12-weeks duration in puppies less than 6 months of age. Bravecto is not effective against Amblyomma americanum ticks beyond 8 weeks after dosing (see Effectiveness). Adverse Reactions: In a well-controlled U.S. field study, which included 294 dogs (224 dogs were administered Bravecto every 12 weeks and evidence of eliminal product.				effective
Contraindications: There are no known contraindications for the use of the product. Warnings: Not for human use. Keep this and all drugs out of the reach of children. Keep the product in the original packaging until use, in order to prevent children from getting direct access to the product. Do not eat, drink or smoke while handling the product. Wash hands thoroughly with soap and water immediately after use of the product. Precautions: Bravecto has not been shown to be effective for 12-weeks duration in puppies less than 6 months of age. Bravecto is not effective against Amblyomma americanum ticks beyond 8 weeks after dosing (see Effectiveness). Adverse Reactions: In a well-controlled U.S. field study, which included 294 dogs (224 dogs were administered Bravecto every 12 weeks and vere provided with a tick called the second of a very decided.	>44.0 - 88.0	1000	One	demonst 48 hours
Contraindications: There are no known contraindications for the use of the product. Warnings: Not for human use. Keep this and all drugs out of the reach of children. Keep the product in the original packaging until use, in order to prevent children from getting direct access to the product. Do not eat, drink or smoke while handling the product. Wash hands thoroughly with soap and water immediately after use of the product. Precautions: Bravecto has not been shown to be effective for 12-weeks duration in puppies less than 6 months of age. Bravecto is not effective against Amblyomma americanum ticks beyond 8 weeks after dosing (see Effectiveness). Adverse Reactions: In a well-controlled U.S. field study, which included 294 dogs (224 dogs were administered Bravecto every 12 weeks and evidence of the provided with a tick cells of the colors.	>44.0 - 88.0 >88.0 - 123.0*	1000	One	demonst 48 hours 72 hours
There are no known contraindications for the use of the product. Warnings: Not for human use. Keep this and all drugs out of the reach of children. Keep the product in the original packaging until use, in order to prevent children from getting direct access to the product. Do not eat, drink or smoke while handling the product. Wash hands thoroughly with soap and water immediately after use of the product. Precautions: Bravecto has not been shown to be effective for 12-weeks duration in puppies less than 6 months of age. Bravecto is not effective against Amblyomma americanum ticks beyond 8 weeks after dosing (see Effectiveness). Adverse Reactions: In a well-controlled U.S. field study, which included 294 dogs (224 dogs were administered Bravecto every 12 weeks and evident active control every 4 weeks and were provided with a tick collective state.	>44.0 - 88.0 >88.0 - 123.0* *Dogs over 123.0 lb should be administer	1000 1400 ed the appropriate combination of chews	One One	on dogs effective demonst 48 hours 72 hours In a well- flea allerg
Warnings: Not for human use. Keep this and all drugs out of the reach of children. Keep the product in the original packaging until use, in order to prevent children from getting direct access to the product. Do not eat, drink or smoke while handling the product. Wash hands thoroughly with soap and water immediately after use of the product. Precautions: Bravecto has not been shown to be effective for 12-weeks duration in pupples less than 6 months of age. Bravecto is not effective against Amblyomma americanum ticks beyond 8 weeks after dosing (see Effectiveness). Adverse Reactions: In a well-controlled U.S. field study, which included 294 dogs (224 dogs were administered Bravecto every 12 weeks and evidence and administered and oral active control every 4 weeks and were provided with a tick called the severy 12 weeks and evidence and oral active control every 4 weeks and were provided with a tick called the severy 12 weeks and evidence and oral active control every 4 weeks and were provided with a tick called the severy 12 weeks and evidence and oral active control every 4 weeks and were provided with a tick called the severy 12 weeks and evidence and oral active control every 4 weeks and were provided with a tick called the severy 12 weeks and evidence and oral active control every 4 weeks and were provided with a tick called the severy 12 weeks and evidence and oral active control every 4 weeks and were provided with a tick called the severy 12 weeks and evidence and oral active control every 4 weeks and were provided with a tick called the severy 12 weeks and evidence and oral active control every 4 weeks and were provided with a tick called the severy 12 weeks and evidence and oral active control every 4 weeks and were provided with a tick called the severy 12 weeks and evidence and oral active control every 4 weeks and were provided with a tick called the severy 12 weeks and evidence and 12 weeks a	>44.0 – 88.0 >88.0 – 123.0* *Dogs over 123.0 lb should be administen Treatment with Bravecto may begin at an	1000 1400 ed the appropriate combination of chews	One One	effective demonst 48 hours 72 hours In a well- flea allerg of elimin
Not for human use. Keep this and all drugs out of the reach of children. Keep the product in the original packaging until use, in order to prevent children from getting direct access to the product. Do not eat, drink or smoke while handling the product. Wash hands thoroughly with soap and water immediately after use of the product. Precautions: Bravecto has not been shown to be effective for 12-weeks duration in puppies less than 6 months of age. Bravecto is not effective against Amblyomma americanum ticks beyond 8 weeks after dosing (see Effectiveness). Adverse Reactions: In a well-controlled U.S. field study, which included 294 dogs (224 dogs were administered Bravecto every 12 weeks and evidence of the product. Animal Margin and 5X There we clinical organ incider did so organ and some provided with a tick collective source.	>44.0 - 88.0 >88.0 - 123.0* *Dogs over 123.0 lb should be administen Treatment with Bravecto may begin at an Contraindications:	1000 1400 ed the appropriate combination of chews ny time of the year and can continue year r	One One	effective demonst 48 hours 72 hours In a well- flea allerg of elimin
product. Wash hands thoroughly with soap and water immediately after use of the product. Precautions: Bravecto has not been shown to be effective for 12-weeks duration in puppies less than 6 months of age. Bravecto is not effective against Amblyomma americanum ticks beyond 8 weeks after dosing (see Effectiveness). Adverse Reactions: In a well-controlled U.S. field study, which included 294 dogs (224 dogs were administered Bravecto every 12 weeks and 70 dogs were administered an oral active control every 4 weeks and were provided with a tick collection.	>44.0 – 88.0 >88.0 – 123.0* *Dogs over 123.0 lb should be administen Treatment with Bravecto may begin at an Contraindications: There are no known contraindications fo	1000 1400 ed the appropriate combination of chews ny time of the year and can continue year of the use of the product.	One One ound without interruption.	effective demonst 48 hours 72 hours In a well- flea allerg
Bravecto has not been shown to be effective for 12-weeks duration in puppies less than 6 months of age. Bravecto is not effective against Amblyomma americanum ticks beyond 8 weeks after dosing (see Effectiveness). Adverse Reactions: In a well-controlled U.S. field study, which included 294 dogs (224 dogs were administered Bravecto every 12 weeks and 70 dogs were administered an oral active control every 4 weeks and were provided with a tick collection.	>44.0 - 88.0 >88.0 - 123.0* *Dogs over 123.0 lb should be administen Treatment with Bravecto may begin at ar Contraindications: There are no known contraindications fo Warnings: Not for human use. Keen this and all dri	1000 1400 ed the appropriate combination of chews ny time of the year and can continue year of the use of the product.	One One ound without interruption.	effective demonst 48 hours 72 hours In a well- flea allerg of elimin Palatabi voluntar when of
Adverse Reactions: In a well-controlled U.S. field study, which included 294 dogs (224 dogs were administered Bravecto every 12 weeks and 70 dogs were administered an oral active control every 4 weeks and were provided with a tiple collection.	>44.0 – 88.0 >88.0 – 123.0* *Dogs over 123.0 lb should be administen Treatment with Bravecto may begin at ar Contraindications: There are no known contraindications fo Warnings: Not for human use. Keep this and all dru	1000 1400 ed the appropriate combination of chews my time of the year and can continue year or the use of the product. ugs out of the reach of children. Keep the atting direct access to the great access	One One ound without interruption. product in the original packaging until	effective demonst 48 hours 72 hours In a well flea allere of elimin Polatabi voluntar when of Animal Margin of Marian In a well of the second
Adverse Reactions: In a well-controlled U.S. field study, which included 294 dogs (224 dogs were administered Bravecto every 12 weeks and 70 dogs were administered an oral active control every 4 weeks and were provided with a tiple collection.	>44.0 – 88.0 >88.0 – 123.0* *Dogs over 123.0 lb should be administen Treatment with Bravecto may begin at ar Contraindications: There are no known contraindications fo Warnings: Not for human use. Keep this and all druse, in order to prevent children from ge product. Wash hands thoroughly with so	ags out of the reach of children. Keep the etting direct access to the product.	One One One ound without interruption. product in the original packaging until eat, drink or smoke while handling the product.	effective demonst 48 hour. 72 hours In a well flea aller of elimin Palatabi voluntat when of Animal Margin and 5X.
	>44.0 – 88.0 >88.0 – 123.0* *Dogs over 123.0 lb should be administen Treatment with Bravecto may begin at ar Contraindications: There are no known contraindications fo Warnings: Not for human use. Keep this and all druse, in order to prevent children from geproduct. Wash hands thoroughly with so Precautions: Bravecto has not been shown to be efferenced.	and the appropriate combination of chews any time of the year and can continue year or the use of the product. Augs out of the reach of children. Keep the exting direct access to the product. Do not cap and water immediately after use of the crive for 12 weeks.	One One One ound without interruption. product in the original packaging until eat, drink or smoke while handling the product.	effective demonsta 48 hours 72 hours In a well flea allen of elimin Palatabi voluntar when of Animal Margin and 5X There w clinical organ
	>44.0 – 88.0 >88.0 – 123.0* *Dogs over 123.0 lb should be administer. Treatment with Bravecto may begin at an Contraindications: There are no known contraindications fo Warnings: Not for human use. Keep this and all druse, in order to prevent children from ge product. Wash hands thoroughly with so Precautions: Bravecto has not been shown to be effective against Amblyomma americant.	and the appropriate combination of chews by time of the year and can continue year of the use of the product. The use of the product. The use of the reach of children. Keep the enting direct access to the product. Do not pap and water immediately after use of the cities for 12-weeks duration in puppies less than ticks beyond 8 weeks after dosing (see	One One One ound without interruption. product in the original packaging until eat, drink or smoke while handling the product. than 6 months of age. Bravecto is not Effectiveness).	effective demonst 48 hours 72 hours In a well-flea allert of elimin Palatabi voluntar when of Animal Margin and 5X There we clinical organ vincider
	>44.0 – 88.0 >88.0 – 123.0* *Dogs over 123.0 lb should be administer Treatment with Bravecto may begin at ar Contraindications: There are no known contraindications fo Warnings: Not for human use. Keep this and all druse, in order to prevent children from ge product. Wash hands thoroughly with so Precautions: Bravecto has not been shown to be effective against Amblyomma americant Adverse Reactions: In a well-controlled U.S. field study, white 70 dogs were administered an oral active	and the appropriate combination of chews by time of the year and can continue year of the use of the product. The use of the product. The use of the reach of children. Keep the etting direct access to the product. Do not pap and water immediately after use of the country of the use of the use of the country of the use of the use of the use of the country of the use of t	One One One ound without interruption. product in the original packaging until eat, drink or smoke while handling the product. than 6 months of age. Bravecto is not Effectiveness).	effective demonst 48 hours 72 hours In a well-flea allert of elimin Palatabi voluntar when of Animal Margin and 5X 1 There we clinical organ incider did so eviden
	>44.0 – 88.0 >88.0 – 123.0* *Dogs over 123.0 lb should be administer Treatment with Bravecto may begin at ar Contraindications: There are no known contraindications fo Warnings: Not for human use. Keep this and all druse, in order to prevent children from ge product. Wash hands thoroughly with so Precautions: Bravecto has not been shown to be effective against Amblyomma americant Adverse Reactions: In a well-controlled U.S. field study, white 70 dogs were administered an oral active	and the appropriate combination of chews by time of the year and can continue year of the use of the product. The use of the product. The use of the reach of children. Keep the etting direct access to the product. Do not pap and water immediately after use of the country of the use of the use of the country of the use of the use of the use of the country of the use of t	One One One ound without interruption. product in the original packaging until eat, drink or smoke while handling the product. than 6 months of age. Bravecto is not Effectiveness).	effective demonst 48 hours 72 hours In a well-flea allert of elimin Palatabi voluntar when of Animal Margin and 5X 1 There we clinical organ incider did so eviden
	>44.0 – 88.0 >88.0 – 123.0* *Dogs over 123.0 lb should be administer Treatment with Bravecto may begin at ar Contraindications: There are no known contraindications fo Warnings: Not for human use. Keep this and all druse, in order to prevent children from ge product. Wash hands thoroughly with so Precautions: Bravecto has not been shown to be effective against Amblyomma americant Adverse Reactions: In a well-controlled U.S. field study, white 70 dogs were administered an oral active	and the appropriate combination of chews by time of the year and can continue year of the use of the product. The use of the product. The use of the reach of children. Keep the etting direct access to the product. Do not pap and water immediately after use of the country of the use of the use of the country of the use of the use of the use of the country of the use of t	One One One ound without interruption. product in the original packaging until eat, drink or smoke while handling the product. than 6 months of age. Bravecto is not Effectiveness).	effective demonst 48 hours 72 hours In a well-flea allerg of elimin voluntar when of Animal Margin and 5X t There we clinical organ vinciden did so eviden
	>44.0 – 88.0 >88.0 – 123.0* *Dogs over 123.0 lb should be administer Treatment with Bravecto may begin at ar Contraindications: There are no known contraindications fo Warnings: Not for human use. Keep this and all druse, in order to prevent children from ge product. Wash hands thoroughly with so Precautions: Bravecto has not been shown to be effective against Amblyomma americant Adverse Reactions: In a well-controlled U.S. field study, white 70 dogs were administered an oral active	and the appropriate combination of chews by time of the year and can continue year of the use of the product. The use of the product. The use of the reach of children. Keep the etting direct access to the product. Do not pap and water immediately after use of the country of the use of the use of the country of the use of the use of the use of the country of the use of t	One One One ound without interruption. product in the original packaging until eat, drink or smoke while handling the product. than 6 months of age. Bravecto is not Effectiveness).	effective demonst 48 hours 72 hours In a well- flea allerg of elimin Palatabii voluntar

That in a "margin of safety study," "there were no clinically-relevant, treatment related effects":

		Bravecto Group: Percentage of Dogs with the AR During the	Active Control Group: Percentage of Dogs with the AR During the	a dose of up to 10 dogs in the control	
	Vomiting	182-Day Study (n=224 dogs)	84-Day Study (n=70 dogs)	There were no	
	Decreased Appetite	7.1	14.3	performance ser	
		6.7	0.0	One adult treater salivation was ob	
	Diarrhea	4.9	2.9	The following ab	
cazol-3-yl]-2-	Lethargy	5.4	7.1	examination: lim	
2	Polydipsia	1.8	4.3	veterinary exami treated group ha	
	Flatulence	1.3	0.0	necropsy (days	
es felis), and	In a well-controlled laboratory dose on		AMOUNT TO SERVICE OF THE SERVICE OF	In a well-contro	
nerican dog d older, and	intervention by the next morning.	offirmation study, one dog developed eden dema improved progressively through the	e day and had resolved without medical	Storage Inform Do not store ab	
stations for	Additional information can be found a reporting for animal drugs, contact SafetyHealth. Clinical Pharmacology:	uspected adverse drug reaction, contact t t www.bravecto.com. For additional info FDA at 1-888-FDA-VETS or online a	Merck Animal Health at 1-800-224-5318. rmation about adverse drug experience t http://www.fda.gov/AnimaiVeterinary/	How Supplied: Bravecto is avaindividually into 1, 2, or 4 chews	
	Peak fluralaner concentrations are achie	ved between 2 hours and 2 days following	g oral administration, and the elimination	NADA 141-415,	
n ticks (see	effectiveness) through 112 days. Due to with food.			Distributed by: Intervet Inc (d/i Madison, NJ 07	
	Mode of Action:			Made in Austri	
	Fluralaner is for systemic use and belon inhibitor of the arthropod nervous syster channels (gamma-aminobutyric acid (GA Effectiveness:		d benzamide derivatives. Fluralaner is an antagonism of the ligand-gated chloride	Copyright © 20 All rights reserv	
	Bravecto began to kill fleas within two laboratory study, Bravecto killed fleas and on dogs by > 989% within 12 hours for effectiveness against adult fleas 48 hour demonstrated ≥ 93% effectiveness again 48 hours post-infestation for 12 weeks. 72 hours post-infestation for 8 weeks, but in a well-controlled U.S. field study, a sing flea allergy dermatitis showed improvement of eliminating flea infestations. Palatability: In a well-controlled U.S. field voluntarily consumed Bravecto within 5 rown offered with food, and 6.8% refused.	17 Weeks. In a well-controlled laborator the nur 12 weeks. In a well-controlled laborator is post-infestation for 12 weeks. In well st Dermocentor variabilis, Ixodes scapus Bravecto demonstrated ≥90% effective trailed to demonstrate ≥90% effective ple dose of Bravecto reduced fleas by ≥ it in erythema, alopecia, papules, scales at study, which included 559 doses administration and official to the property of t	nbers of live fleas and <i>knodes ricinus</i> ticks ry study, Bravecto demonstrated 100% -controlled laboratory studies, Bravecto laris and <i>Rhipicephalus sanguineus</i> ticks eness against <i>Amblyomma americanum</i> less beyond 8 weeks. 99.7% for 12 weeks. Dogs with signs of crusts, and excoriation as a direct result		
g until ng the	Animal Safety: Margin of Safety Study: In a margin of safe and 5X the maximum label dose of 56 mg/l	ty Study Brauento was administra			
is not	There were no clinically-relevant, treatment-related effects on physical examinations, body weights, food consumption, clinical pathology (hematology, clinical chemistries, coagulation tests, and urinalysis), gross pathology, histopathology, or organ weights. Diarrhea, mucoid and bloody feces were the most common observations in this study, occurring at a similar incidence in the treated and control groups. Five of the twelve treated dogs that experienced one or more of these signs did so within 6 hours of the first dosing. One dog in the 3X treatment group was observed to be dull, inappetant, with evidence of bloody diarrhea, vomiting, and weight loss beginning five days after the first treatment. One dog in the 1X treatment group yomited food 4 hours following the first treatment.				
		3,000	and the period in the property with		

And that in a "reproductive safety study," "there were no clinically-relevant, treatment related effects" even though "one adult treated dog suffered a seizure during the course of the study (46 days after treatment)":



B. Complaints of Neurological Adverse Events Relating to Isoxazoline Flea and Tick Products Prompt FDA to Issue Warning and Label Change.

25. During the time period relevant to this action, Plaintiff and the other class members were exposed to and saw Bravecto's labeling and/or other deceptive marketing claims in which Defendant omitted or otherwise failed to disclose of adverse neurological reactions from taking Bravecto. Defendant failed to inform any of the class members about the significant risks Bravecto posed to animals who take it. Defendant's uniform representations would be understood by the average, reasonable consumer that Bravecto was free from defects and safe for its intended use that formed the basis of Plaintiff's and the other class members' bargain with Defendant. Plaintiff's and the other class members' Bravecto purchases were direct transactions between themselves and Defendant, because Bravecto came with packaging and materials prepared by Defendant, including representations and warranties that Bravecto was safe and free from defects.

- 26. Since its launch in 2014, thousands of consumers and veterinarians have reported adverse events relating to isoxazoline flea and tick treatments, including from Bravecto. Information obtained through public records requests to the FDA, and its European counterpart the European Medicines Agency ("EMA"), demonstrate that animals treated with isoxazoline medications experienced consistent neurological adverse reactions, including but not limited to, death, seizures, shaking/tremors/ataxia, neurological/cognitive issues, muscular/balance issues and vomiting/loss of appetite.
- 27. On September 20, 2018, more than four years after Defendant began marketing and selling Bravecto, the FDA issued its Press Release warning pet owners and veterinarians of the potential risk of neurological adverse events associated with isoxazoline medications to treat flea and ticks, including Bravecto. As a result of the adverse events, the FDA requested that manufacturers change their labels to disclose these risks, so that veterinarians and pet owners could make an informed decision as to whether they want to use these treatments on their pets. The FDA Press Release stated, in pertinent part:

The U.S. Food and Drug Administration is alerting pet owners and veterinarians to be aware of the potential for neurologic adverse events in dogs and cats when treated with drugs that are in the isoxazoline class.

Since these products have obtained their respective FDA approvals, data received by the agency as part of its routine post-marketing activities indicates that some animals receiving Bravecto (fluralaner) tablets for dogs, Bravecto (fluralaner) topical solution for cats and dogs, Nexgard (afoxalaner) tablets for dogs, or Simparica (sarolaner) tablets for dogs, have experienced adverse events such as muscle tremors, ataxia, and seizures. Two additional products in this class, Credelio (lotilaner) tablets for dogs and Revolution Plus (selamectin and sarolaner topical solution) for cats, recently received FDA approval. These products are approved for the treatment and prevention of flea infestations, and the treatment and control of tick infestations. Revolution Plus, is also approved for prevention of heartworm disease, treatment and control of ear mite infestations and some gastrointestinal parasite infections.

The FDA is working with manufacturers of isoxazoline products to include new label information to highlight neurologic events because these events were seen consistently across the isoxazoline class of products. Revolution Plus, which was approved most recently, includes the new labeling information to highlight the potential for neurologic events in the isoxazoline class, and Merial has made the requested changes to Nexgard's labeling including adding the new class statement. Merial has since transferred ownership of Nexgard's approval to Boehringer Ingelheim.

The FDA carefully reviewed studies and other data on Bravecto, Bravecto Topical, Credelio, Nexgard, Simparica and Revolution Plus prior to approval, and these products continue to be safe and effective for the majority of animals. The agency is asking the manufacturers to make the changes to the product labeling in order to provide veterinarians and pet owners with the information they need to make treatment decisions for each pet on an individual basis. Veterinarians should use their specialized training to review their patients' medical histories and determine, in consultation with pet owners, whether a product in the isoxazoline class is appropriate for the pet.

Although FDA scientists carefully evaluate an animal drug prior to approval, there is the potential for new information to emerge after marketing, when the product is used in a much larger population. In the first three years after approval, the FDA pays particularly close attention to adverse event reports, looking for any safety information that may emerge.⁵

28. The FDA Press Release indicated that certain manufacturers had made the requested label change. As of the date of the FDA Press Release, Defendant had not disclosed the risk of neurological adverse reactions from ingestion or application of Bravecto.

C. Defendant Knew That Bravecto Products Were Defective During the Class Period and Failed to Take Remedial Action.

29. Based on its composition as a pesticide that is ingested or applied to animals and absorbed into their blood stream in order to penetrates nervous systems and cause death of insects, and complaints concerning neurological adverse reactions since Bravecto was released to the

⁵ FDA Press Release, https://www.fda.gov/animal-veterinary/cvm-updates/animal-drug-safety-communication-fda-alerts-pet-owners-and-veterinarians-about-potential-neurologic (Sept. 20, 2018, updated in April and August 2019).

market in 2014 and through at least late 2018, Defendant knew of these risks that it never disclosed to consumers and their veterinarians. Defendant knew that because of these undisclosed risks, it was depriving consumers and their veterinarians of the ability to make an informed decision as to whether to use Bravecto on their pets.

- 30. According to a parasitology expert at the College of Veterinary Medicine at the University of Illinois Urbana-Champaign, "Isoxazoline class medications bind to chloride channels in nerve and muscle cells, which blocks the transmission of neuronal signals, causing parasites to become paralyzed and die." The expert also stated that, "[isoxazoline class medications] can still cause toxicity in mammals, depending on the animal's physiological state, health, and history."
- 31. In contrast to Bravecto and other isoxazoline products, other flea and tick treatments are only applied to an animal's skin on a monthly basis. They are not absorbed into the animal's blood stream. Instead, they are stored in the animal's oil glands on its skin such that when insects come in contact with the animal's coat—not through biting them as with isoxazoline products, they die.⁷
- 32. Before the FDA approved Bravecto for market, safety studies and clinical trials indicated that isoxazoline drugs could cause neurologic adverse reactions in animals. For example,

⁶ College of Veterinary Medicine, University of Illinois Urbana-Champaign, FDA Alert on Flea Medication (Oct. 22, 2018), https://vetmed.illinois.edu/pet_column/fda-alert-on-flea-medications/ ("Only medications in the isoxazoline class of flea and tick medications are under investigation at this time. This includes Bravecto, Nexgard, Credelio, and Simparica (brand names for fluralaner, afoxolaner, lotilaner, and sarolaner).")

⁷ Frontline, FAQ, https://frontline.com/plus/Pages/Faq.aspx (last visited Dec. 27, 2019).

in September 2013, the FDA approved NexGard, the first isoxazoline product to be sold in the U.S. NexGard discloses on its label and website this risk, stating in part:

In the U.S. field study, one dog with a history of seizures experienced a seizure on the same day after receiving the first dose and on the same day after receiving the second dose.... This dog experienced a third seizure one week after receiving the third dose. The dog remained enrolled and completed the study. Another dog with a history of seizures had a seizure 19 days after the third dose of NexGard. The dog remained enrolled and completed the study. A third dog with a history of seizures received NexGard and experienced no seizures throughout the study.

- 33. Unlike Bravecto, however, other isoxazoline products, including Simparica approved in February 2016, and Credelio approved in January 2018, also disclose risks of neurological adverse reactions on their websites and labels. The Simparica label, for example, states that during its studies a dog experienced ataxia and six of sixteen puppies given three times and five times the recommended dose of Simparica had a variety of neurologic signs.⁹
- 34. As of the date of this Complaint, Defendant now discloses, as a "Precaution," the risk of neurologic adverse reactions from Bravecto, including tremors, ataxia, and seizures. Defendant, however, downplays and minimizes these risks as being uncommon and most prevalent in animals with a history of seizures, even though seizures have occurred in animals without any such history, like Plaintiff's dog, Jake, including:

⁸ VIN News, Alert on pet flea control draws questions, few answers, Oct. 5, 2018 https://news.vin.com/vinnews.aspx?articleId=50328 (last visited Dec. 27, 2019).

⁹ *Id*.

*Bravecto kills fleas, prevents flea infestations, and kills ticks (black-legged tick, American dog tick, and brown dog tick) for 12 weeks. Bravecto also kills lone star ticks for 8 weeks.

Important Safety Information: Bravecto has not been shown to be effective for 12-weeks' duration in puppies less than 6 months of age. Bravecto is not effective against lone star ticks beyond 8 weeks of dosing. Fluralaner is a member of the isoxazoline class. This class has been associated with neurologic adverse reactions including tremors, ataxia, and seizures. Seizures have been reported in dogs receiving isoxazoline class drugs, even in dogs without a history of seizures. Use caution in dogs with a history of seizures or neurologic disorders. Bravecto Chew. The most commonly reported adverse reactions include vomiting, decreased appetite, diarrhea, lethargy, polydipsia, and flatulence. Bravecto Topical Solution for Dogs: The most commonly reported adverse reactions include vomiting, hair loss, diarrhea, lethargy, decreased appetite, and moist dermatitis/rash. For topical use only. Avoid oral ingestion.



Copyright © 2019 Intervet Inc., d/b/a Merck Animal Health, a subsidiary of Merck & Co., Inc. All rights reserved.

Important Safety Information: *Use caution in dogs with a history of seizures*. Seizures have been reported in dogs receiving fluralaner, even in dogs without a history of seizures. ¹⁰

35. Defendant's website for Bravecto *now* discloses, in pertinent part:

IMPORTANT SAFETY INFORMATION

BRAVECTO has not been shown to be effective for 12-weeks' duration in puppies or kittens less than 6 months of age. Fluralaner is a member of the isoxazoline class. This class has been associated with neurologic adverse reactions including tremors, ataxia, and seizures. BRAVECTO Chew: The most commonly reported adverse reactions include vomiting, decreased appetite, diarrhea, lethargy, polydipsia, and flatulence. BRAVECTO is not effective against lone star ticks beyond 8 weeks of dosing. Seizures have been reported in dogs receiving isoxazoline class drugs, even in dogs without a history of seizures. Use with caution in dogs with a history of seizures or neurologic disorders. BRAVECTO Topical Solution for Dogs: The most commonly reported adverse reactions include vomiting, hair loss, diarrhea, lethargy, decreased appetite, and moist dermatitis/rash. Bravecto is not effective against lone star ticks beyond 8 weeks of dosing. For topical use only. Avoid oral ingestion. Seizures have been reported in dogs receiving isoxazoline class drugs, even in dogs without a history of seizures. Use caution in dogs with a history of seizures or neurologic disorders.

^{1.}

¹⁰ Chewy, Bravecto, https://www.chewy.com/bravecto-chews-dogs-44-88-lbs-1/dp/172909?utm source=google-

product&utm_medium=cpc&utm_campaign=p&utm_content=Bravecto&utm_term=&gclid=EA_ IaIQobChMIuvyH4e3M5gIVJ4FaBR1fzQbLEAQYASABEgILrfD_BwE (last visited Dec. 23, 2019) (emphasis added); https://www.chewy.com/bravecto-chews-dogs-44-88-lbs-1/dp/172909?utm_source=google-

<u>product&utm_medium=cpc&utm_campaign=p&utm_content=Bravecto&utm_term=&gclid=EA_laIQobChMIuvyH4e3M5gIVJ4FaBR1fzQbLEAQYASABEgILrfD_BwE_last visited Dec. 23, 2019).</u>

BRAVECTO Topical Solution for Cats: The most commonly reported adverse reactions include vomiting, itching, diarrhea, hair loss, decreased appetite, lethargy, and scabs/ulcerated lesions. BRAVECTO is not effective against American dog ticks beyond 8 weeks of dosing. For topical use only. Avoid oral ingestion. The safety of BRAVECTO has not been established in breeding, pregnant and lactating cats. Neurologic adverse reactions have been reported in cats receiving isoxazoline class drugs, even in cats without a history of neurologic disorders. Use with caution in cats with a history of neurologic disorders. 11

36. Defendant's 2019 label in Canada for Bravecto warns of the risk of "Neurological disorders: convulsions, ataxia, muscle tremor," and its package insert includes the following:

The following adverse events have been reported rarely: 1 (reported in at least 1 but not more than 10 animals in 10,000 animals exposed) and very rarely: 2 (reported in less than 1 in 10,000 animals exposed) and are listed by body system, in decreasing order of frequency:

Digestive tract disorders: vomiting, diarrhea, hypersalivation, hemorrhagic diarrhea Systemic disorders: lack of efficacy, lethargy, anorexia

Skin and appendage disorders: pruritus, alopecia

Neurological disorders: convulsions, ataxia, muscle tremor. 12

37. As a result of Defendant's failure to fully disclose the neurological risks associated with Bravecto and continued misrepresentations about Bravecto's purported safety and efficacy, consumers suffered and continue to sustain damages resulting from Defendant's misconduct.

¹¹ Bravecto, https://us.bravecto.com/for-dogs (last visited Dec. 24, 2019); https://www.merck-animal-health-usa.com/pdfs/canine/BravectoDogPI_152451%20R11_8.5x11.pdf (last visited Dec. 27, 2019, emphasis added) ("Use with caution in dogs with a history of seizures. Seizures have been reported in dogs receiving fluralaner, even in dogs without a history of seizures (see Adverse Reactions and Animal Safety). . . . Adverse Reactions: In a well-controlled U.S. field study, which included a total of 165 households and 321 treated dogs (221 with fluralaner and 100 with a topical active control), there were no serious adverse reactions" and mentions two dogs without a history experienced seizures.); https://www.chewy.com/frontline-plus-flea-tick-medium-breed/dp/34716 (last visited Dec. 10, 2019) (discloses risk of temporary irritation to animal's skin where applied).

¹² Drugs.com, Bravecto Chewable Tablets, https://www.drugs.com/vet/bravecto-chewable-tablets-1000-mg-can.html (last visited Dec. 24, 2019).

- 38. Plaintiff and members of the proposed Classes have suffered injury as a result of Defendant's concealment, misrepresentations and/or deceptive and unfair trade practices, and are entitled to relief.
- 39. Had Defendant disclosed the risks of adverse neurological reactions associated with Bravecto, Plaintiff and the other Class member would have been aware of these risks and would not have purchased Bravecto, or would not have paid the price that they paid for it. In the future, if Defendant disclosed these risks, Plaintiff and others would be in a position to make an informed decision as to whether to purchase Bravecto at the prices offered.
- 40. Plaintiff and the other class members did not receive the benefit of their bargain with Defendant. Rather, they purchased products that are of a lesser standard, grade, and quality than represented, with undisclosed health and safety risks, or a lack warning of the same. Plaintiff and the other class members did not receive products that met ordinary and reasonable consumer expectations regarding safety and efficacy.

V. <u>PLAINTIFF'S SPECIFIC FACTS</u>

- 41. On November 13, 2016, Plaintiff Valerie Palmieri paid \$49.99 for one Bravecto chewable tablet (for dogs 44-88 pounds), which she purchased from her veterinarian in Trumbull, Connecticut, to treat Jake, her then-78 pound German Shepherd. When she purchased Bravecto, Defendant's packaging and materials did not disclose any risk of neurological adverse reactions. Additionally, Defendant did not inform veterinarians about the safety issues that Bravecto posed to pets. Following her purchase, Ms. Palmieri fed the Bravecto tablet to Jake.
- 42. The next day, November 14, 2016, Jake began to vomit, stopped eating, and began to exhibit other symptoms of lethargy. Ms. Palmieri took her dog to the animal emergency clinic

at Newtown Veterinary Specialists, in Newtown, Connecticut, on November 26, 2016, after Jake was no longer able to walk.

- 43. The emergency veterinarian diagnosed Jake as having a seizure and kept him overnight on an intravenous dosage of Valium. Shortly thereafter, and trying to determine what could have caused his illness, Ms. Palmieri called Defendant to discuss Jake's potentially-adverse reaction after consuming Bravecto. In response to Ms. Palmieri's description of the situation, Defendant denied that Jake's illness could have been caused by Bravecto, but immediately offered to pay for the emergency room visit—only if she signed an agreement releasing her claims. Ms. Palmieri refused to release her claims, because she did not know if Jake's symptoms would be long-term in nature, or if they were even caused by Bravecto. Despite offering to cover her emergency room costs—albeit demanding a release in exchange therefor—Defendant continued to assure Ms. Palmieri that Jake's reactions were unrelated to Bravecto.
- 44. After conducting several additional tests, Ms. Palmieri's veterinarian referred her to a neurologist, who performed an MRI on Jake on December 12, 2016, and diagnosed him with meningitis. On December 28, 2016, after further tests came back negative, ruling out potential causes of the inflammation including bacterial infections, Ms. Palmieri's veterinarian told her that he "presumed" that Jake's meningitis was the result of "Bravecto toxicity"—a conclusion directly contrary to what Defendant represented to Ms. Palmieri a month before.
- 45. Since Jake's diagnosis on December 28, 2016, Ms. Palmieri has not treated Jake with Bravecto, and has not purchased additional Bravecto tablets.
- 46. Since ingesting Bravecto, Jake has continued to experience neurological episodes, including when—in September 2019—he lost his balance and fell down a flight of stairs breaking

his leg. Ms. Palmieri has paid tens of thousands of dollars in treating Jake after his ingestion of Bravecto.

VI. TOLLING OF THE STATUTE OF LIMITATIONS

Fraudulent Concealment

- 47. All applicable statutes of limitation have been tolled by Defendant's knowing, active, and ongoing fraudulent concealment and denial of the facts alleged herein at all times relevant to this action.
- 48. Since before its FDA-approval, and at least as soon after its market launch in 2014 when neurological adverse reactions were observed in the market after widespread use of Bravecto, Defendant knew of the product defect alleged herein. At all times relevant to this action, thousands of similar complaints have been reported alleging adverse neurological reactions as a result of using Bravecto.
- 49. Although the FDA, in May 2014, approved Bravecto for sale in the United States, it was not until September 20, 2018, that the FDA issue a public statement warning pet owners, including putting Plaintiff on notice that her dog's neurological adverse reactions were, in fact, related to Bravecto, and veterinarians about potential neurological adverse events associated with the isoxazoline class of drugs used to treat and prevent flea and tick infestations, including Bravecto. At that time, the FDA requested that manufacturers of isoxazoline products change their products' labels to disclose the risk of neurological events. Manufacturers of some isoxazoline products, including Revolution Plus and Nexgard, changed their label to include this information, but, as of the date of the FDA Press Release, Defendant had not changed Bravecto's label and did not recall the products in circulation to ensure that an adequate warning of the risk of neurological adverse reactions appeared on all of its product packaging.

- 50. Despite knowing about the product defect, Defendant concealed the nature of the defect. Defendant did not disclose the risk of neurological adverse reactions when such risks were clearly known, and, once disclosed, sought to minimize the severity of the risks.
- 51. Any applicable statutes of limitation have, therefore, been tolled by Defendant's knowledge, active concealment, and denial of the facts alleged herein, which behavior remains ongoing.

Discovery Rule

- 52. Plaintiff and the other class members did not immediately discover—and could not have discovered through the exercise of reasonable diligence—the full and complete nature of the Bravecto defect.
- 53. Within the period of any applicable statutes of limitation, Plaintiff and the other Class members could not have discovered, through the exercise of reasonable diligence, that Defendant was—and still is—concealing the Bravecto defect and misrepresenting Bravecto's safety (or lack thereof).
- 54. Any applicable statutes of limitation have, therefore, been tolled by operation of the discovery rule.

Estoppel

- 55. Defendant was under a continuous duty to disclose to Plaintiff and the other class members the true character, quality, and nature of the Bravecto defects.
- 56. Defendant actively concealed Bravecto's true character, quality, and nature and knowingly misrepresented—or omitted—facts about Bravecto's safety, quality, reliability, characteristics, and performance.

- 57. Plaintiff and the other class members reasonably relied upon Defendant's misrepresentations and/or active concealment of these facts.
- 58. Based on the foregoing, Defendant is estopped from relying on any statutes of limitation in defense of this action.

VII. CLASS ACTION ALLEGATIONS

59. The class members' claims all derive directly from a uniform course of conduct by the Defendant. Specifically, Defendant has engaged in uniform and standardized conduct in not disclosing, concealing, and omitting the serious, and dangerous, side effects of its medications. The objective facts—Defendant's failure to disclose, concealment, and omissions—are the same for all class members. Accordingly, Plaintiff brings this lawsuit as a class action on her own behalf and on behalf of all other persons similarly situated as members of the proposed Classes pursuant to Federal Rules of Civil Procedure 23(a) and (b)(3) and/or (b)(2) and/or (c)(4). This action satisfies all requirements of those provisions, including numerosity, commonality, typicality, adequacy, predominance, and superiority.

The Nationwide Class

60. Plaintiff brings this action and seek to certify and maintain it as a class action under Rules 23(a); (b)(2); and/or (b)(3); and/or c(4) of the Federal Rules of Civil Procedure on behalf of herself and a Nationwide Class defined as follows:

All purchasers or users of Bravecto products in the United States or its territories between May 1, 2014 and the present.

The State Subclass

61. Plaintiff alleges a statewide class action claims on behalf of persons in Connecticut (the "Subclass"):

All purchasers or users of Bravecto products in Connecticut between May 1, 2014 and the present.

- 62. Excluded from the Classes are: (a) any person who purchased Bravecto for resale and not for personal or household use, (b) any person who signed a release of any Defendant in exchange for consideration in excess of the cost of Bravecto, (c) Defendant, including any entity or division in which Defendant have a controlling interest, as well as their agents, representatives, officers, directors, employees, trustees, parents, children, heirs, assigns, and successors, and other persons or entities related to, or affiliated with Defendant, and (d) the Judges to whom this case or its predecessor cases were assigned before consolidation, their staffs, and their immediate families. Plaintiffs reserve the right to modify or amend these Nationwide and Statewide Class definitions as appropriate during the course of this litigation.
- Nationwide Class and State Subclass are so numerous and geographically dispersed that individual joinder of all class members is impracticable. While Plaintiff is informed and believes that there are at least thousands of class members, the precise number is unknown to Plaintiff but may be ascertained from purchase records, sales records, production records, and veterinarian records. Plaintiff anticipates providing Court-approved, appropriate notice to class members, to be approved by the Court in accordance with Rule 23 of the Federal Rule of Civil Procedure.
- 64. Commonality and Predominance: Federal Rules of Civil Procedure 23(a)(2) and 23(b)(3). This action involves common questions of law and fact, which predominate over any questions affecting individual class members, including, without limitation:
 - a. Whether Bravecto suffers from a defect;
 - b. Whether the Defendant knew or should have known about the product

defect, and, if so, how long the Defendant have known of the defect;

- c. Whether the defective nature of Bravecto constitutes a material fact that reasonable consumers would have considered in deciding whether to purchase the product;
- d. Whether Defendant had a duty to disclose the defective nature of Bravecto to Plaintiff and class members;
- e. Whether Defendant omitted and failed to disclose material facts about Bravecto;
- f. Whether Defendant's conduct tolls any or all applicable limitations periods by acts of fraudulent concealment, application of the discovery rule, or equitable estoppel;
 - g. Whether Defendant negligently misrepresented that Bravecto is safe;
- h. Whether Defendant engaged in unfair, deceptive, unlawful and/or fraudulent acts or practices in trade or commerce by objectively misleading Plaintiff and putative class members;
- i. Whether Defendant's conduct, as alleged herein, was likely to mislead a reasonable consumer;
- j. Whether Defendant violated state consumer protection laws, and if so, what remedies are available under those statutes;
- k. Whether Defendant's statements, concealments and omissions regarding the Bravecto was material, in that a reasonable consumer could consider them important in purchasing Bravecto;
- 1. Whether Bravecto was unfit for the ordinary purposes for which it was used, in violation of the implied warranty of merchantability;
 - m. Whether Plaintiff and the Classes are entitled to a declaratory judgment

stating that Bravecto is defective and/or not merchantable;

- n. Whether Defendant's unlawful, unfair, and/or deceptive practices harmed Plaintiff and the Classes;
- o. What aggregate amounts of statutory penalties are sufficient to punish and deter Defendant and to vindicate statutory and public policy;
- p. Whether, as a result of Defendant's omissions and/or negligent misrepresentations of material facts, Plaintiff and members of the Class have suffered an ascertainable loss of monies and/or property and/or value; and
- q. Whether Plaintiff and class members are entitled to monetary damages and/or other remedies and, if so, the nature of any such relief.
- 65. **Typicality: Federal Rule of Civil Procedure 23(a)(3)**. Plaintiff's claims are typical of other class members' claims because Plaintiff Classes were subjected to the same allegedly unlawful conduct and damaged in the same way. The relief Plaintiff seeks is typical of the relief sought for the absent class members.
- 66. Adequacy of Representation: Federal Rule of Civil Procedure 23(a)(4). Plaintiff is an adequate class representative because her interests do not conflict with the interests of the other members of the Classes she seeks to represent, Plaintiff has retained counsel competent and experienced in complex class action litigation, and Plaintiff intends to prosecute this action vigorously. The class members' interests will be fairly and adequately protected by Plaintiffs and their counsel.
- 67. **Declaratory and Injunctive Relief: Federal Rule of Civil Procedure 23(b)(2)**. The prosecution of separate actions by individual class members would create a risk of inconsistent or varying adjudications with respect to individual class members that would establish

incompatible standards of conduct for Defendant. Such individual actions would create a risk of adjudications that would be dispositive of the interests of other class members and impair their interests. Defendant has acted and/or refused to act on grounds generally applicable to the Classes, making final injunctive relief or corresponding declaratory relief appropriate.

68. Superiority: Federal Rule of Civil Procedure 23(b)(3). A class action is superior to any other available means for the fair and efficient adjudication of this controversy, and no unusual difficulties are likely to be encountered in the management of this class action. The damages or other financial detriment suffered by Plaintiff and the other class members are relatively small compared to the burden and expense that would be required to individually litigate their claims against Defendant, so it would be impracticable for Class members to individually seek redress for Defendant's wrongful conduct. Even if the class members could afford litigation, the court system could not. Because of the relatively small size of the individual class members' claims (compared to the cost of litigation), it is likely that only a few class members could afford to seek legal redress for Defendant's misconduct. Individualized litigation creates a potential for inconsistent or contradictory judgments and increases the delay and expense to all parties and the court system. By contrast, the class action device presents far fewer management difficulties and provides the benefits of single adjudication, economies of scale, and comprehensive supervision by a single court. Class treatment of common questions of law and fact would be a superior method to multiple individual actions or piecemeal litigation in that class treatment will conserve the resources of the courts and the litigants, and will promote consistency and efficiency of adjudication.

VIII. CLAIMS FOR RELIEF

COUNT I VIOLATION OF THE NEW JERSEY CONSUMER FRAUD ACT N.J. Stat. Ann. § 56.8-19

- 69. Plaintiff realleges and incorporates by reference the preceding paragraphs 1 through 68 as if set forth fully herein.
- 70. Plaintiff brings this claim on behalf of the Nationwide Class under New Jersey law, because New Jersey has the most significant relationship to the issues and facts relevant to this claim, Defendant chose this forum and law, and there is no conflict of law with Connecticut.
- 71. Bravecto was designed, manufactured, advertised, marketed and sold by Defendant, are is considered "merchandise" within the meaning of the New Jersey Consumer Fraud Act. Plaintiff and the Nationwide class members are "persons" and "consumers" with the meaning of the New Jersey Consumer Fraud Act.
- 72. Defendant affirmatively misrepresented Bravecto to consumers. These misrepresentations include, but are not limited to: its false and misleading statements, representations, and depictions in its labeling, packaging, marketing, promotion and advertising of Bravecto as a "safe" flea and tick treatment; the fact that contrary to these representations Bravecto contained toxic pesticide and Defendant failed to provide adequate warning or notice of the risk of neurological adverse reactions to pets because of this; and that because of these misrepresentations and omissions Plaintiff and the Nationwide Class suffered damages.
 - 73. Defendant's claims therefore were false, misleading and/or deceptive.

- 74. Defendant's affirmative misrepresentations and material omissions constituted an unconscionable commercial practice, deception, fraud, false promise, and/or misrepresentation as to the nature of the goods, in violation of the New Jersey Consumer Fraud Act.
- 75. As a result of Defendant's misrepresentations and material omissions, Plaintiff and the Nationwide Class have suffered ascertainable losses of money and property, which they seek to recover consisting of at least the following:
 - a. The damages associated with loss of the benefit of the bargain to the class members pursuant to Rule 23(b)(3) of the Federal Rules of Civil Procedure;
 - b. Consequential damages caused by taking Bravecto (including, but not limited to, veterinary bills incurred as a result of illness, injury or death caused by consuming Bravecto; bills incurred for the disposition of the remains of animals killed by Bravecto; and the market value of the animals killed as a result of taking Bravecto) pursuant to Rule 23(c)(4) of the Federal Rules of Civil Procedure;
- 76. Plaintiff and other Nationwide class members demand judgment pursuant to N.J.S.A. § 56:8-19 against Defendant for its ascertainable damages, statutory remedies made available under the Act, injunctive relief requiring Defendant to adequately disclose the risk of Bravecto.
- 77. Plaintiff and the Nationwide Class further seek to enjoin such unlawful deceptive acts and practices as described above. Each of the Nationwide class members will be irreparably harmed unless the unlawful actions of Defendant are enjoined, in that Defendant will continue to falsely and misleadingly market, advertise and represent on its packaging that Bravecto is a "safe" flea and tick treatment for animals to consume or to be applied to their skin. Toward that end, Plaintiff and the Nationwide Class request an order pursuant to Rule 23(b)(2) of the Federal Rules

of Civil Procedure granting them injunctive relief requiring corrective disclosures and/or disclaimers on the labeling and advertising of Bravecto.

78. Absent injunctive relief, Defendant will continue to manufacture and sell unsafe and misrepresented Bravecto products without adequate warnings to consumers of their health risks.

79. Defendant has violated, and continues to violate, the New Jersey Consumer Fraud Act, which makes deception, fraud, false promise, and/or misrepresentation of goods unlawful. As a direct and proximate result of Defendant's violation of the New Jersey Consumer Fraud Act, as described above, Plaintiff and the members of the Nationwide Class have suffered damages, as set forth above.

COUNT II BREACH OF EXPRESS WARRANTY N.J.S.A. § 12A:2-313

- 80. Plaintiff realleges and incorporates by reference the preceding paragraphs 1 through 68 as if set forth fully herein.
- 81. Plaintiff brings this claim on behalf of the Nationwide Class under New Jersey law, because New Jersey has the most significant relationship to the issues and facts relevant to this claim and Defendant chose this forum and law. In the alternative, Plaintiff brings this claim, on behalf of herself and on behalf of the Subclass, under the laws of Connecticut where Plaintiff and Subclass Members reside and/or purchased Bravecto.
- 82. Defendant constitutes a "merchant" and a "seller" in connection with their sales of Bravecto to Plaintiff and the Nationwide Class as those terms are defined in the New Jersey Uniform Commercial Code. Plaintiff and the Nationwide Class constituted "buyers" as that term

is defined in the New Jersey Code. Bravecto products constituted "goods" as that term is defined in the New Jersey Code.

- 83. Under section 2-313 of title 12A of the New Jersey Revised Statutes, Defendant's statements of affirmations of fact, promises and descriptions made on Bravecto's packaging and advertising, which Defendant provided to Plaintiff and the Nationwide Class, created written express warranties before or at the time of purchase, including that Bravecto was safe for pets to treat fleas and ticks.
- 84. These affirmations of facts and promises made by Defendant to Plaintiff and the Nationwide Class related to Bravecto and became part of the bases of the bargains for the purchase of Bravecto between them and Defendant, and thereby created express warranties that Bravecto would conform to those affirmations and promises.
- 85. Furthermore, the aforementioned descriptions of Bravecto were part of the bases of the bargains for the purchases of Bravecto between Defendant on the one hand and Plaintiff and individual members of the Nationwide Class on the other. The descriptions created an express warranty that the goods would conform to those descriptions.
- 86. As previously noted, Defendant misrepresented the nature of Bravecto as safe without serious health risks. Instead, Bravecto is a toxic pesticide that presents a risk of neurological adverse reactions to animals. Bravecto did not conform to the affirmations, promises and descriptions previously mentioned, resulting in breaches of Bravecto's express warranties.
- 87. Plaintiff complied with all conditions precedent to filing this breach of warranty claim, including providing notice of the breach of warranty to Defendant on behalf of herself and the Nationwide Class, prior to filing this action. Alternatively, the filing of this Amended Complaint provides sufficient notice of breach to Defendant on behalf of Plaintiff and the

Nationwide Class. Alternatively, notice need not have been given to Defendant because it had actual notice of its breaches of warranty as to Plaintiff and the Nationwide Class.

- 88. As a direct and proximate result of Defendant's breach of express warranties, Plaintiff and the Nationwide Class have suffered actual damages as follows:
 - a. Compensatory damages amounting to, among other things, the difference in value between the full purchase price of Bravecto and the actual value of it, pursuant to Rule 23(b)(3) of the Federal Rules of Civil Procedure; and
 - b. Consequential damages pursuant to Rule 23(c)(4) of the Federal Rules of Civil Procedure.
- 89. Plaintiff and the Nationwide Class demand judgment against Defendant for damages, as set forth above, plus interest, costs and such additional relief as the Court may deem appropriate or to which Plaintiff and the Nationwide Class may be entitled.

COUNT III PRODUCTS LIABILITY N.J. Stat. Ann. § 2A:58C-2

- 90. Plaintiff realleges and incorporates by reference the preceding paragraphs 1 through 68 as if set forth fully herein.
- 91. Defendant designed, manufactured and sold Bravecto, an unsafe toxic pesticide that creates a risk of neurological adverse reactions.
- 92. Bravecto was not reasonably fit, suitable or safe for its intended purpose because it contains toxic pesticide and failed to contain adequate warnings of the risk of neurological adverse reactions.

93. The misrepresentations that made the consumption of the Bravecto risky to the health of animals was, at all times material hereto, an unreasonably dangerous defect and/or condition. The failure of Defendant to warn on its package of the dangerousness of Bravecto also constituted an unreasonably dangerous defect and/or condition.

94. These unreasonably dangerous defects and/or conditions existed at the time Bravecto left Defendant control.

95. Bravecto came in sealed packages, and its packaging did not change from the time it left Defendant's possession through the time they arrived in stores or veterinarians' offices to be sold to consumers, and consumers purchased and took possession of it.

96. The unreasonably dangerous defects and/or conditions of Bravecto proximately caused injury and death to animals, constituting property damage to Plaintiff and certain other members of the Nationwide Class beyond and in addition to the damages from purchasing the mislabeled and worthless Bravecto.

97. Accordingly, Defendant is strictly liable for the damages caused to Plaintiff and any other members of the Nationwide Class, by the unreasonably dangerous Bravecto, specifically the illness and deaths of any animals and the expenses incurred therewith.

COUNT IV UNJUST ENRICHMENT

- 98. Plaintiff realleges and incorporates by reference the preceding paragraphs 1 through 68 as if set forth fully herein.
- 99. Plaintiff brings this claim on behalf of the Nationwide Class under New Jersey law, because New Jersey has the most significant relationship to the issues and facts relevant to this claim, Defendant chose this forum and law. In the alternative, Plaintiff brings this claim, on behalf

of herself and on behalf of the Subclass, under the laws of Connecticut where Plaintiff and Subclass members reside and/or purchased Bravecto.

- 100. Defendant's unlawful, unfair, deceptive, and wrongful acts and omissions, unjustly enriched Defendant at the expense of Plaintiff and the Nationwide Class.
- 101. Plaintiff and Nationwide class members paid a premium for Bravecto, which was unfit for its ordinary use.
- 102. Plaintiff and Nationwide class members conferred a benefit on Defendant through payment for the misrepresented and defective Bravecto.
- 103. Defendant's retention of the benefit conferred as a result of its unlawful acts was inequitable and unjust.
 - 104. Plaintiff and members of the Nationwide Class have no adequate remedy at law.
- 105. Plaintiff and members of the Nationwide Class are entitled to seek restitution and other relief from Defendant, including an order requiring Defendant to disgorge all profits, benefits, and other compensation obtained by Defendant through and for its wrongful conduct.

COUNT V VIOLATION OF THE MAGNUSON-MOSS WARRANTY ACT 15 U.S.C. § 2301

- 106. Plaintiff realleges and incorporates by reference the preceding paragraphs 1 through68 as if set forth fully herein.
- 107. Plaintiff brings this Count against the Defendant on behalf of members of the Nationwide Class. In the alternative, Plaintiff brings this claim on behalf of the Subclass.
- 108. This Court has jurisdiction to decide claims brought under 15 U.S.C. § 2301 by virtue of 28 U.S.C. § 1332 (a)-(d).

- 109. Plaintiff and others like her are "consumers" within the meaning of the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301(3) and are persons entitled under applicable state law to enforce against the warrantor the obligations of its express and implied warranties.
- 110. Defendant is a "supplier[s]" and "warrantor[s]" within the meaning of the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301(4)-(5).
- 111. Bravecto is a "consumer products" within the meaning of the Magnuson- Moss Warranty Act, 15 U.S.C. § 2301(1).
- 112. The Magnuson-Moss Warranty Act, 15 U.S.C. § 2310(d)(1), provides a cause of action for any consumer, who is damaged by the failure of a warrantor to comply with a written or implied warranty.
- 113. Defendant made promises and representations in an express warranty provided to all consumers, which became the basis of the bargain between Plaintiff, class members and Defendant.
- 114. Defendant' written affirmations of fact, promises and/or descriptions as alleged—including promises that Bravecto was "safe," is a "written warranty." The affirmations of fact, promises and/or descriptions constitute a "written warranty" within the meaning of the Magnuson-Moss Act, 15 U.S.C. §2301(6).
- 115. Further, Defendant provided Plaintiff and the other Nationwide class members with an implied warranty of merchantability in connection with the purchase of Bravecto that is an "implied warranty" within the meaning of the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301(7).
- 116. As a part of the implied warranty of merchantability, Defendant warranted to Plaintiff and Nationwide class members that Bravecto was of merchantable quality (*i.e.*, a product

of a high enough quality to make it fit for sale, usable for the purpose it was made, of average worth in the marketplace, or not broken, unworkable, contaminated or flawed or containing a defect affecting the safety of the product), would pass without objection in the trade or business, and was free from material defects, and reasonably fit for the use for which it was intended.

- 117. Defendant breached all applicable warranties, as described in more detail above, and is therefore liable to Plaintiff and the Nationwide Class pursuant to 15 U.S.C. § 2310(d)(1). Without limitation, Bravecto suffers from latent and/or inherent defects that cause adverse neurological reactions rendering Bravecto unfit for its intended use and purpose. This defect substantially impairs the use, value and safety of Bravecto.
- 118. Any effort to limit the implied warranties in a manner that would exclude coverage of Bravecto is unconscionable, and any such effort to disclaim, or otherwise limit, liability for the defective Bravecto products is null and void. Any limitations on the warranties are procedurally unconscionable. There was unequal bargaining power between the Defendant, on the one hand, and Plaintiff and the other Nationwide class members, on the other. Moreover, any limitations on the warranties are substantively unconscionable. Following early reports of injuries caused by Bravecto, Defendant knew that Bravecto was defective and would continue to pose safety risks to pets. Defendant failed to disclose the product defect to Plaintiff and the Nationwide class members. Thus, Defendant's enforcement of any durational limitations on those warranties is harsh and shocks the conscience.
- 119. Plaintiff and each of the other Nationwide class members have had sufficient direct dealings with Defendant to establish privity of contract.

- 120. All conditions precedent to seeking liability under this claim for breach of express and implied warranty have been performed by or on behalf of Plaintiff and others in terms of paying for the goods at issue.
- 121. Pursuant to 15 U.S.C. § 2310(e), Plaintiff and the Nationwide Class are entitled to bring this class action and are not required to give Defendant notice and an opportunity to cure until such time as the Court determines the representative capacity of Plaintiff and the Nationwide Class pursuant to Rule 23 of the Federal Rules of Civil Procedure.
- 122. Furthermore, affording Defendant an opportunity to cure its breach of written warranties would be unnecessary and futile here. Defendant was placed on reasonable notice of the defect in Bravecto based on numerous complaints received directly and indirectly from Plaintiff and the Nationwide Class, and have had ample opportunity to cure the defect for Plaintiff and the Nationwide Class, but have failed to do so. Under the circumstances, the remedies available under any informal settlement procedure would be inadequate and any requirement that Plaintiff and the Nationwide Class resort to an informal dispute resolution procedure and/or afford Defendant a reasonable opportunity to cure the breach of warranty is excused and thereby deemed satisfied.
- 123. Defendant' breaches of warranty have caused Plaintiff and the other Nationwide class members to suffer injuries, paying for defective products, and entering into transactions they would not have entered into for the consideration paid. As a direct and proximate result of Defendant' breaches of warranty, Plaintiff and the Nationwide Class have suffered damages and continue to suffer damages, including economic damages in terms of the cost of Bravecto and the cost of efforts to mitigate the damages caused by same.

124. The amount in controversy of this action exceeds the sum of \$50,000, exclusive of interest and costs, and Plaintiff's individual claim exceeds \$25, computed on the basis of all claims to be determined in this lawsuit. Plaintiff, individually and on behalf of the other Nationwide class members, seeks all damages permitted by law and equity in an amount to be proven at trial. In addition, pursuant to 15 U.S.C. § 2310(d)(2), Plaintiff and the other Nationwide class members are entitled to recover a sum equal to the aggregate amount of costs and expenses (including attorneys' fees based on actual time expended) determined by the Court to have reasonably been incurred by Plaintiff and the other Nationwide class members in connection with the commencement and prosecution of this action.

COUNT VI Connecticut Unfair Trade Practices Act C.G.S.A. § 42-110g

Plaintiff, on behalf of the State Subclass

- 125. Plaintiff realleges and incorporates by reference the preceding paragraphs 1 through 68 as if set forth fully herein.
 - 126. Plaintiff asserts this claim individually and on behalf of the Connecticut Subclass.
 - 127. Defendant is a "person" as defined by C.G.S.A. § 42-110a(3).
- 128. Defendant is engaged in "trade" or "commerce" as those terms are defined by C.G.S.A. § 42-110a(4).
- 129. At the time of filing this Complaint, Plaintiff has sent notice to the Attorney General and Commissioner of Consumer Protection pursuant to C.G.S.A. § 42-110g(c). Plaintiff will provide a file-stamped copy of the Complaint to the Attorney General and Commissioner of Consumer Protection.
- 130. Defendant advertised, offered, or sold goods or services in Connecticut, and engaged in trade or commerce directly or indirectly affecting the people of Connecticut.

- 131. Defendant engaged in deceptive acts and practices and unfair acts and practices in the conduct of trade or commerce, in violation of the C.G.S.A. § 42-110b, including: (i) Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or qualities that they do not have; (ii) Representing that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another; and (iii) Engaging in any other unconscionable, false, misleading, or deceptive act or practice in the conduct of trade or commerce.
- 132. Defendant's representations and omissions were material because they were likely to deceive reasonable consumers.
- 133. Defendant intended to mislead Plaintiff and Connecticut Subclass members and induce them to rely on its misrepresentations and omissions.
- 134. Had Defendant disclosed to Plaintiff and Connecticut Subclass members that it uniformly misrepresented Bravecto as a "safe" flea and tick treatment, omitted material information regarding risk of neurological adverse reactions, and was otherwise engaged in deceptive, common business practices, Defendant would have been unable to continue in business and it would have been forced to disclose the uniform defects in Bravecto. Instead, Defendant represented that Bravecto was a safe flea and tick treatment without disclosing the risk of any serious adverse reactions. Plaintiff and the Connecticut Subclass members acted reasonably in relying on Defendant's misrepresentations and omissions, the truth of which they could not have discovered.
- 135. Defendant acted intentionally, knowingly, and maliciously to violate the Connecticut Unfair Trade Practices Act, and recklessly disregarded Plaintiff and Connecticut

Subclass members' rights. Defendant's knowledge of the adverse neurological reactions to Bravecto put Defendant on notice that the Bravecto was not as safe as advertised.

- 136. As a direct and proximate result of Defendant's deceptive acts and practices, Plaintiff and Connecticut Subclass members have suffered and will continue to suffer injury, ascertainable losses of money or property, and monetary and non-monetary damages, including from not receiving the benefit of their bargain in purchasing Bravecto and paying veterinarian bills for treatment relating to the neurological adverse reactions in their pets after consuming Bravecto.
- 137. Defendant's deceptive acts and practices caused substantial, ascertainable injury to Plaintiff and Connecticut Subclass members, which they could not reasonably avoid, and which outweighed any benefits to consumers or to competition.
- 138. Defendant's violations of Connecticut law were done with reckless indifference to the Plaintiff and the Connecticut Subclass or was with an intentional or wanton violation of those rights.
- 139. Plaintiff requests damages in the amount to be determined at trial, including statutory and common law damages, attorneys' fees, and punitive damages, under Rules 23(b)(2), (b)(3), and (c)(4) of the Federal Rules of Civil Procedure.

IX. REQUEST FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf of all other class members, respectfully requests that the Court enter judgment in her favor and against Defendant as follows:

- a. Certifying the Class and Subclass as requested herein, designating Plaintiff as Class Representative, and appointing the undersigned counsel as Class Counsel;
- b. Declaring that Defendant is financially responsible for notifying the class members of the pendency of this suit;

- c. Awarding actual (e.g., compensatory and consequential) and/or statutory damages (including exemplary or punitive damages) to the maximum extent allowed in an amount to be proven at trial;
- d. Requiring restitution and disgorgement of all profits and unjust enrichment Defendant obtained from Plaintiff and the other class members as a result of Defendant's unlawful, unfair, and/or fraudulent business practices;
- e. Awarding injunctive relief as permitted by law or equity, including enjoining Defendant from continuing the unlawful practices as set forth herein, and ordering Defendant to engage in a corrective advertising campaign;
- f. Awarding Plaintiff her reasonable attorneys' fees, costs, and expenses;
- g. Awarding pre- and post-judgment interest on any amounts awarded; and
- h. Awarding such other and further relief as may be just and proper.

X. JURY DEMAND

Plaintiff hereby demands a trial by jury on all issues so triable.

December 27, 2019

Respectfully submitted,

/s/ Mark A. DiCello

MARK A. DICELLO

N.J. Bar No. 306102019

madicello@dicellolevitt.com

DICELLO LEVITT GUTZLER LLC

Western Reserve Law Building

7556 Mentor Avenue

Mentor, Ohio 44060

Telephone: (440) 953-8888

ADAM J. LEVITT (pro hac vice to be sought)

alevitt@dicellolevitt.com

AMY E. KELLER (*pro hac vice* to be sought)

akeller@dicellolevitt.com

DICELLO LEVITT GUTZLER LLC

Ten North Dearborn Street, Eleventh Floor

Chicago, Illinois 60602

Telephone: (312) 214-7900

JESSICA J. SLEATER

jessica@andersensleater.com

ANDERSEN SLEATER SIANNI LLC

1250 Broadway, 27th Floor New York, New York 10001 Telephone: (646) 599-9848

RALPH N. SIANNI rsianni@andersensleater.com **ANDERSEN SLEATER SIANNI LLC** 2 Mill Road, Suite 202 Wilmington, Delaware 19806 Telephone: (302) 510-8528

Counsel for Plaintiff and the Proposed Class